Caring

Geisinger

Geisinger IRB Member Orientation – Session 3

Informed Consent & HIPAA Authorization – Process, Document, Waiver & Alteration

Debra L. Henninger, MHSA BSN RN CCRC

Informed Consent

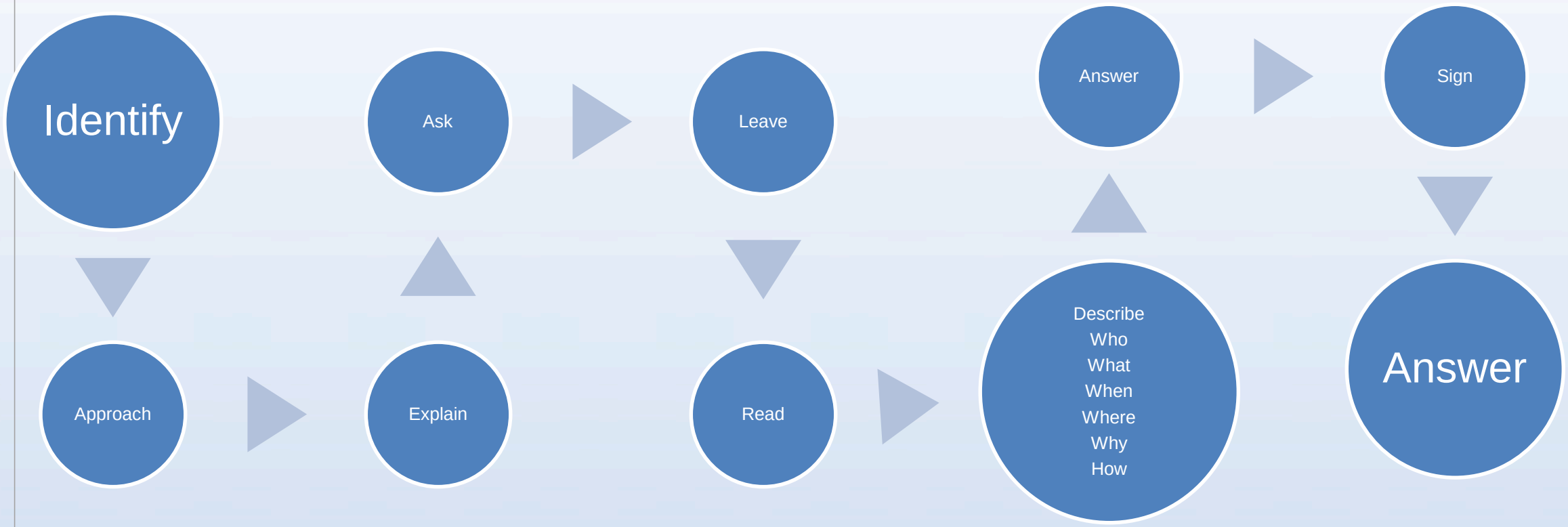
45 CFR 46.116

Geisinger

45 CFR 46.116 General requirements for informed consent

- Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
- An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.
- No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Consent is more than a form, it's a PROCESS … repeats throughout study



Geisinger

Consent Process

- ✓How are ‘potential’ participants identified?
- ✓How are ‘potential’ participants approached?
- ✓How is the study introduced?
- ✓Who introduces the study?
- ✓Who obtains consent?
- ✓How do you determine if the patient understands the study?

Geisinger

Consent Process – iRIS Study Application

6.0 Written Consent
6.1 Describe the setting and conditions under which consent/assent will be obtained, including parental permission or surrogate permission and the steps taken to ensure subjects' independent decision-making.
6.2 List all personnel who will be involved in the consent process, which includes the consent interview, etc.
6.3 Describe the waiting period between informing the prospective participant and obtaining consent? If none, please provide justification.
6.4 Specify the documents that will be used during the consent/assent process. Copies of all documents should be appended to the protocol, in the same format that they will be given to subjects.
6.5 Explain provisions in place to ensure comprehension for research involving non-English speaking subjects. Translated copies of all consent materials must be submitted for approval prior to use.
6.6 Indicate how the personnel obtaining consent will assess the potential subject's ability and capacity to consent to the research being proposed.

Geisinger

Required Elementsof Informed Consent

45 CFR 46.116

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/checklists/#

Geisinger

1. Research Purpose and Procedures

- ✓ Statement that the study involves research
- ✓ Purpose of the study
- ✓ Duration of participation
- ✓ Description of procedures
- ✓ Identify what is experimental
  - ✓ “What activities are only being done for research purposes?”
  - ✓ “What activities are part of participant’s routine/usual care?”

Geisinger

Study involves research – Consent Template

Title of Form: ***Research Consent /Authorization Form***

Section Heading: ***We are asking you to be in a health research study.***

Geisinger

Purpose of the study – Consent Template

Why is this study being done?

*We are asking you to join this study because you have ***.*
*We want to learn more about ***.*

We are asking people like you to help us.

Geisinger

Duration of Participation – Consent Template

How long will I be in the study?

*You will be in the research study for about ***.*

The study doctor could decide to take you off this research study if:

- *The doctor believes it is in your best interest*
- *You do not follow the study direction*
- *For any other reason*

Geisinger

Description of procedures – Consent Template

What will I be asked to do?

Add general statements. Use table/schedule of events for specific visit information.

If applicable:

What will happen to my [blood, urine, tissue]?

Include how much is collected, where samples will be stored, for how long and if it can be redacted.

Explain what is experimental – Consent Template

What are the costs?

Use Section A or B based on the study Billing Determination:

Section A:

All visits, tests and procedures listed under "What will I be asked to do?" are done for the study only. They will be done at no cost to you or your insurance company.

You or your insurance company will be charged for the costs of your routine care (the care you would have received if you were not in this study).

Section B: A color/letter-coded schedule of events or other easily displayed cost information is recommended. However, a bulleted list can be used. Use only the sections below that are applicable.

2. Risks and Discomforts

- ✓ Description of foreseeable risks and/or discomforts
  - ✓ Physical
  - ✓ Psychological
  - ✓ Social
  - ✓ Financial

Geisinger

14

Risks & Discomforts – Consent Template

What are the risks?

There are risks related to your (illness/condition) and routine care. This form will not list those risks. We will only list the added risks of being in this study.

Insert Risks Diagrams, pictographs or color coding can be used. Provide probability of harm.

There might be effects that we do not know about yet.

Geisinger

3. Potential Benefits

- ✓ Reasonable expected benefits to participant
- ✓ Reasonable expected benefits to others / society

Geisinger

16

Potential Benefits – Consent Template

Can being in this study help me?

This study might or might not help you. We hope that what is learned from this study will help others in the future. Add any known benefits.

Geisinger

4. Alternate Procedures or Treatments

- ✓ Description of any alternative treatments for condition being studied, if any, that might be advantageous to the participant

Geisinger

18

Alternate treatment – Consent Template

Do I have other choices?

You do not have to be in this study. You have other choices. You could choose:

- *Usual care for your illness or condition*
- *No treatment*
- *To be in a different study*

Your study doctor will talk to you about your choices.

During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

Geisinger

5. Confidentiality of records identifying the participant

- ✓ Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained

5. Confidentiality … HIPAA Authorization (patients)

HIPAA Authorization to Use and Disclose Information for Research Purposes

- ✓ Meaningful description of PHI that will be used or disclosed
- ✓ Description of each purpose of the requested use and disclosure
- ✓ Who will be using and disclosing PHI
- ✓ Who is PHI disclosed to (e.g., collaborators, sponsor, government agencies, IRB)
- ✓ Information about expiration of the authorization (“end of study” or “none”)
- ✓ Signature of participant and date

5. Confidentiality … HIPAA Authorization (patients)

HIPAA Authorization to Use and Disclose Information for Research Purposes

- ✓ Participant's right to revoke Authorization in writing; exceptions to that right; how to revoke
- ✓ Notice that Geisinger's cannot condition clinical treatment, payment, benefits on the Authorization, but can condition participation in study and research-related treatment (consequences of not signing)
- ✓ Potential for re-disclosure of PHI once released and no longer protected by Privacy Rule

Geisinger

Confidentiality / HIPAA Authorization – Consent Template

How will Geisinger use and share my information?

*The Geisinger study staff will view and collect information that is in your medical record. We will collect information about you during this study. Some of this information will be kept in a research record at Geisinger. These records will be kept for at least *** and then destroyed. Any information placed in your medical record will be a permanent part of your medical record.*

Your primary care doctor or specialist (may/will) receive information about your participation in this study.

We will share your information with the study sponsor. If applicable: Staff working for [sponsor] could be present during your procedure at Geisinger.

Geisinger

Confidentiality / HIPAA Authorization – Consent Template

By signing this form, you are giving Geisinger permission to use and share your health information until the end of this study. (OR for research databases or repositories: By signing this form, you are giving us permission to use and share your health information indefinitely.) *If you change your mind, tell us in writing to stop using and sharing your information. Write to:* [Enter name of study, internal zip code and address] *Information already collected will still be used. We will only use and share new information if it is needed to protect your safety or follow with the law.*

Confidentiality / HIPAA Authorization – Consent Template

How will others use and share my information?

The information shared with [sponsor] will include: Only include the bullets that are applicable to your study. Add a second list if another group will receive a different set of patient information.

- *Initials*
- *Date of Birth*
- *Study ID number*
- *Medical history (including dates)*
- *Information about the medical care you receive during the course of the study (including dates)*
- *Device model and serial number*
- *Images from your study procedures (your name and medical record number will be removed)*
- If you will be sharing information related to drug and alcohol use, illegal behaviors, sexual attitudes, describe here
- If you will be sharing information related to mental health, describe here. Link to guidance
- *HIV test results*

Confidentiality / HIPAA Authorization – Consent Template

The information sent to the [sponsor] and its partners may be kept and used without end.

If applicable:

A group of experts, who do not work for the sponsor, will review the progress and safety of this research study.

Geisinger

Confidentiality / HIPAA Authorization – Consent Template

Your research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by: Only include the bullets that are applicable to your study.

- *Geisinger Institutional Review Board*
- *Geisinger staff*
- *The Food and Drug Administration (FDA),*
- *Department of Health and Human Services (DHHS)*
- *Office for Human Research Protections (OHRP)*
- *[sponsor] and its partners*
- *Government agencies in other countries*

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify you.

Geisinger

Confidentiality – Consent Template

How is my information protected?

We will take steps to protect your information. Add a description of the steps taken. *Some laws that protect your information only apply to hospitals, doctors' offices, and other healthcare providers. When your information is shared outside of Geisinger, some federal privacy laws might not apply.*

We will share your information with a court of law or the government, in the unlikely event this is required.

OR

Certificate of Confidentiality required language (see sponsor's language or https://grants.nih.gov/grants/policy/coc/suggested-language.htm)

Geisinger

6. Research–Related Injury or Illness

- ✓ Studies with greater than minimal risk
- ✓ Description of if & what plans for medical treatment
- ✓ Description of if & what plans for compensation
  - ✓ Clearly state who will pay for treatment if a subject is harmed
  - ✓ Geisinger template language
- ✓ Where to obtain additional information

Geisinger

Injury Language – Consent Template

DRAFT language until the subject injury section of the study contract is finalized

Industry-authored, industry-sponsored studies:

It is GHS policy that industry sponsors pay for research-related subject injury, and this coverage is negotiated in the study contract.

Federally funded studies:

In general, federally funded or foundation funded studies do not provide subject injury.

Geisinger

Template Language: Industry-sponsored studies

What if I am Harmed?

If you are ill or injured due to this study, call your study doctor right away.

Call: [insert name and phone number].

No funds have been set aside to compensate you in the event of injury or illness.

If your illness or injury is due to study tests or the study drug (which is not part of your standard care), (sponsor) will pay for reasonable and customary medical expenses for the diagnosis and treatment of such illness or injury.

Geisinger

Template language: Sponsor is not paying for injuries (eg. NIH studies or cooperative group studies)

What if I am Harmed?

If you are ill or injured due to this study, call your study doctor right away.

Call: [insert name and phone number].

No funds have been set aside to compensate you in the event of injury or illness.

In the case of injury or illness resulting from this research study, medical treatment is available but will be provided at the usual charge. Immediately contact your study doctor [insert name and phone number].

You or your insurance company will also be charged for continuing medical care and/or hospitalization required for any such injury or illness.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

7. Contact Information

- ✓ Research-related injury or illness
- ✓ Questions about the research
- ✓ participants' rights

Geisinger

33

Contact Information – Consent Template

Study Name:

Full Title:

[Study Doctor/Lead Researcher]:

Site(s):

Study Phone Number:

24-Hour Phone Number: 570-271-6211 (Hospital Operator)

Geisinger

Contact Information – Consent Template

What if I am harmed?

If you are ill or injured due to this study, call your study doctor right away.
Call: [name and phone number].

Geisinger

Contact Information – Consent Template

What if I have questions or problems?

For questions about the research study, call the study team.
Call: [name and phone number].

Geisinger has a group of people who are not part of this study that review research to protect your safety, rights, and welfare. If you would like to obtain more information, offer input or discuss problems or concerns about your rights as a research participant, you can call Geisinger Institutional Review Board (IRB) at:

- *844-542-3299 or 570-271-8663 (Danville, PA)*
- *609-449-4395 (Atlantic City, NJ)* [Only add for AtlantiCare studies]

Geisinger

8. Voluntary Participation

- ✓ Statement that participation is voluntary
- ✓ Decision to not participate
  - ✓ No penalty
  - ✓ No loss of benefits
- ✓ May decide to withdraw at any time

Geisinger

37

Voluntary Participation – Consent Template

We are asking you to be in a health research study.

You do not have to be in this study. Your care at Geisinger will not change if you say no. If you join this study, you can stop at any time.

This form tells you about the study. You can ask someone to read it to you. You can ask questions at any time.

Additional Elements of Consent (when appropriate)

1. Unforeseeable Risks to subject or fetus
2. Circumstances for termination by investigator without subject's consent
3. Any additional costs as a result of participation
4. Consequences of subject's decision to withdraw from study and procedures for orderly termination
5. Significant new findings will be shared that may affect a subject's willingness to participate
6. Approximate number of participants to be enrolled

Unforeseeable Risks– Consent Template

There might be effects that we do not know about yet.

New information – Consent Template

During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

Geisinger

Approximate Number – Consent Template

Who will be in the study?

*About *** people will join at Geisinger. About *** will join this study* [worldwide/in the US].

Circumstances for termination – Consent Template

The study doctor could decide to take you off this research study if:

- *The doctor believes it is in your best interest*
- *You do not follow the study direction*
- *For any other reason*

Geisinger

Additional Costs – Consent Template

What are the costs?

If applicable:

The following/items in [insert color/letter] *are done as part of your routine medical care and will be billed to you or your insurance.*

- Add bulleted list of items that apply if not using color/letter-coded graph

You or your insurance company will be charged for the costs of your routine care (the care you would have received if you were not in this study).

Studies with genetic component – GINA language required

"The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This protection does not include life insurance, disability insurance, or long-term care insurance."

Geisinger

GINA – GIRB Consent Template

The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This protection does not apply to life insurance, disability insurance, or long-term care insurance.

Only for AtlantiCare (New Jersey) studies or sub-studies with genetic components:

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. In addition, the New Jersey Genetic Privacy Act protects against discrimination by companies that provide life insurance, annuity and disability insurance coverage. This protection does not apply to long-term care insurance.

FDA-Required for ‘Applicable’ Clinical Trials

If trial is conducted under an IND or subject to FDA regulations

- ✓Registered on www.clinicaltrials.gov
- ✓Include following statement in consent form

“A description of this clinical trial will be available on www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

Commercialization Language (coming) – Consent Template

If this study leads to a marketed product, this product will be the property of the [sponsor]. You will not be entitled to any of the [sponsor]'s financial benefits resulting from this product, the study, or from the use of your samples.

Consent? - iRIS Study Application

5.15 How will informed consent/assent be obtained for the study? *Please check one of the following*

- (•) Written Consent
- ( ) Waiver of written documentation of consent (Verbal consent from subjects will be obtained)
- ( ) Waiver of consent (no consent from subject will be obtained.)

Geisinger

Waiver of Documentation of Informed Consent

(Waiver of signature)

45 CFR 46.116

Geisinger

Waiver of Documentation of Consent

Signed Consent can be waived if:

- ✓ Research presents no more than **minimal risk***

AND

- ✓ Research involves procedures that do not require written consent when performed outside of a research setting

(***Minimal risk-*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

OR

Waiver of Documentation of Consent

- ✓ Principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research,

AND

- ✓ Consent document is the only record linking the subject with the research,

AND

- ✓ Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participants wishes will govern.

Waiver of Documentation of Consent

- ✓ The consent process takes place but participant signatures are not required.
- ✓ The researcher/team document participants decision to participate – spreadsheet, note in EHR or research record
- ✓ Typically used in situations where written consent doesn't make sense

Examples:

- Phone/internet interview study (oral script) for a minimal risk study survey.
- A study where the principal risk would be harm form breach of confidentiality.

6.0 Waiver of written documentation of consent

- Describe the setting and conditions under which consent/assent will be obtained.
- How will you assess the potential subject's ability and capacity to consent?
- Specify and submit the documents that will be used during the consent/assent process.
- Explain provisions for research involving non-English speaking subjects.

Waiver of Documentation of Consent - iRIS Study Application

Waiver of Documentation of Consent

5.15 How will informed consent / assent be obtained for the study? ***Please check one of the following***

- ○ Written Consent
- ◉ Waiver of written documentation of consent (Verbal consent from subjects will be obtained)
- ○ Waiver of consent (no consent from subject will be obtained.)

Geisinger

Waiver of Documentation of Consent - iRIS Study Application

6.0 Waiver of written documentation of consent

6.5	**Would the signed consent form be the only record linking the subject and the research?**
	○ Yes ○ No
6.6	**Does the breach of confidentiality constitute the principal risk to subjects?**
	○ Yes ○ No
6.7	**Does the research pose greater than minimal risk?**
	○ Yes ○ No
6.8	**Does the research include any activities that would require signed consent in a non-research context?**
	○ Yes ○ No

Geisinger

Waiver of Informed Consent

(No consent takes place)

45 CFR 46.116

45 CFR 46.116 General requirements for informed consent

- **Except as provided elsewhere in this policy,** no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
- An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.
- No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Geisinger

Waiver of Informed Consent

The waiver or alteration of requirements for obtaining informed consent:

- This waiver applies in the special circumstances when the IRB determines that it is not necessary to obtain the participants' consent to conduct the research.
- **HHS** regulations allow the IRB to waive the requirement for obtaining informed consent or parental permission or to approve a consent procedure that leaves out or alters some or all of the elements of informed consent otherwise required under the regulations.
- The **FDA** does not allow a waiver or alteration of the requirements for obtaining informed consent except in special circumstances.

Waiver of Informed Consent

1) Research involves **no more than minimal risk** to participants and their privacy,

2) Waiver or alteration will **not adversely affect the rights and welfare** of the participants,

3) Research **could not practicably be conducted** without the waiver or alteration and access to and use of identifiable protected health information,

AND

4) Whenever appropriate (generally, when there is a health justification), the participants will be **provided with additional pertinent information** after participation.

Alteration of Informed Consent

- IRB can approve the elimination or alteration of one or more of the 8 required elements of consent
- Same 4 criteria must be met whether the consent is waived or alteration has been requested.

Additional HIPAA Criteria

The same 4 waiver criteria must be met PLUS the following:

- ✓ Adequate plan to protect identifiers from improper use and disclosure.
- ✓ Adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law,

AND

- ✓ Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for the research for which the use or disclosure of protected health information would be permitted.

Waiver of Informed Consent & HIPAA Authorization

Example: Retrospective reviews of medical records

IRB findings to waive consent for this type of research:

- ✓ Minimal risk
- ✓ Researcher de-identified the information
- ✓ Consent is not easily obtained for large cohort of Geisinger patients

FDA – Wavier of Consent

The IRB cannot grant a waiver of consent or documentation of consent if the research study involves the use of an investigational drug (IND) or device (IDE) that is regulated by FDA and is more than minimal risk.

The only exceptions:

- "emergency use of a test article"
- "planned emergency research"

Geisinger

Waiver of Consent - iRIS Study Application

5.15 How will informed consent/assent be obtained for the study? *Please check one of the following*

- ○ Written Consent
- ○ Waiver of written documentation of consent (Verbal consent from subjects will be obtained)
- ◉ Waiver of consent (no consent from subject will be obtained.)

Geisinger

Waiver of Consent - iRIS Study Application

6.0 Waiver of consent

6.1 Does the research pose greater than minimal risk to subjects?

○ Yes ◉ No

6.2 Will the waiver adversely affect subject' rights and welfare?

○ Yes ◉ No

6.3 Why would the research be impracticable to conduct without the waiver?

6.4 Where appropriate, how will pertinent information be returned to, or shared with subjects at a later date?

Geisinger

HIPAA Authorization - iRIS Study Application

5.17 Are you requesting a Waiver of Authorization for the entire study?

(•) Yes ( ) No

HIPAA Authorization - iRIS Study Application

9.0 Request for Waiver of Authorization

9.1 ***Complete this appendix to request a partial waiver of authorization for recruitment purposes.***

In the main application you indicated the PHI that will be collected as part of this research protocol. Please answer the following questions:

9.2 Explain how the use and disclosure of the information presents no more than minimal risk to the privacy of the individual?

We intend to conduct a data pull for recruitment purposes of this study. This pull will include a limited data set needed in order to properly screen potential study patients. This method presents no more than minimal risk to the patient because the data, including PHI, will be securely pulled by the Biostatistical team at Geisinger and sent to the IRB –approved study team for screening procedures. This listing will be sent via secured e-mail and saved on password protected computers within Geisinger's secure network. Once enrollment goals have been reached, this file will be destroyed.

Geisinger

HIPAA Authorization - iRIS Study Application

9.3 Describe the plan to protect the identifiers from improper use and disclosure (i.e., where will the identifiers will be stored and who will have access.)

No PHI used for screening purposes will be disclosed outside of Geisinger. Only the Geisinger study team and bio-statisticians will have access to patient's PHI. The data pull including PHI will be stored on Geisinger's secure network assessable only to IRB-approved study team members. After enrollment goals have been met, this file will be destroyed.

9.4 Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a health or research justification for retaining identifiers or if such retention is required by law, please provide this information as well.

After enrollment goals have been met for this research study, this data file (including PHI) will be destroyed.

9.5 Explain why the research could not be practicably conducted without the alteration or waiver.

Access to the EHR for eligibility review is necessary to identify potential subjects for this research study. A large number of patients will meet exclusion criteria through use of our data-pull and it would be burdensome to ask all patients for their written authorization to review their medical records for screening purposes prior to confirming that they might be eligible for participation. In addition, it would be impractical to try to identify all potential subjects seen at Geisinger without a data pull.

9.6 Explain why the research could not be conducted without access to and use of the PHI.

Review of PHI is necessary to identify and confirm appropriate patients are approached for participation in the study.

Geisinger

Assent & Parental Permission

45 CFR 46.116

Assent Requirements

Age	Assent (Minimal) Requirements	Signature
< 7	None	None
7-12	Verbal with documentation in the record (i.e., medical record and/or research record)	None
13-17	Verbal with documentation in the record (i.e., medical record and/or research record)	None - *Unless specific requirements dictate that signed assent is obtained, (i.e., request of the IRB, PI, or study sponsor).

Geisinger

Parental Permission Requirements

Research	Signatures
Minimal Risk	1 parent/guardian signature
Greater than Minimal Risk with Direct Prospect of Benefits to Participant	1 parent/guardian signature
Greater than Minimal Risk with No Direct Prospect of Benefits to Participant	2 parents/guardians signatures
Study meets Criteria for Waiver of Documentation of Consent	Waive signatures
Study meets Criteria for Waiver of Documentation of Consent	Waive parental permission *Research is generally not suitable for a waiver if it involves: • mental or psychological problems, • sexual behavior or attitudes, • illegal/antisocial/self-incriminating behavior, • appraisals of other individuals with whom the minor has a familial relationship, • relationships legally recognized as privileged (lawyers, doctors, clergy), or • religious affiliations or beliefs.

Geisinger

Additional Guidance: HRPP webpage – Handbook & Guidance Documents

Accessing Decision-Making Capacity

LAR (Surrogate) Consent

Short Form

Electronic Consent (pending)

Informed consent must contain a statement that the project is research.

TRUE or FALSE?

Geisinger

What risk language must be included in consent for a minimal risk study?

A. Reasonably foreseeable risks and discomforts

B. Risks to the subject, embryo or fetus that are currently unforeseeable

C. Loss of confidentiality

D. Death

E. All of the above

The IRB can approve a waiver of documentation of consent for a study involving participant interviews.

TRUE or FALSE?

Geisinger

The informed consent must include the approximate number of participants to be enrolled.

TRUE or FALSE?

Geisinger

What must be included in the ICF when the study includes genetic testing?

GINA

*The **Genetic Information Nondiscrimination Act of 2008 (GINA),** makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This protection does not include life insurance, disability insurance, or long-term care insurance.*

The informed consent must include subject injury language.

TRUE or FALSE?

Geisinger

Adults provide informed consent via secure website requiring a unique username and password. IRB approves …

A. Written informed consent

B. Waiver of informed consent

C. Waiver of documentation of consent

D. Waiver of informed consent and HIPAA authorization

E. Written assent

QUESTIONS??